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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/804,733	03/13/2001	Qi Wang	MIT 6614.1	2031
32425	7590	11/19/2003	EXAMINER	
FULBRIGHT & JAWORSKI L.L.P. 600 CONGRESS AVE. SUITE 2400 AUSTIN, TX 78701			LEFFERS JR, GERALD G	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 11/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/804,733	WANG ET AL	
	Examiner	Art Unit	
	Gerald G Leffers Jr., PhD	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 August 2003.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-118 is/are pending in the application.
- 4a) Of the above claim(s) 21-118 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6/14/01  
11/7/02
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group V (claims 1-18 and 20 directed to a method for producing a recombinant protein containing two tandem repeat units in a plant cell) in the paper submitted 8/28/03. The traversal is on the ground(s) that: (1) each of Groups I-V, VII-XI, XV-XIV and XX-XXIV is distinguishable only by cell type and this limitation is not the crucial element of the invention, (2) each of these groupings comprises a linking claim, but the examiner has not followed linking claim practice, and (3) it is not a burdensome search to search each of the small peptide sequences recited in the claims (e.g. claim 9).

Upon further consideration of the instant specification and pending claims, and in view of applicants' arguments, restriction amongst Groups I-V, VII-XI, XV-XIV and XX-XXIV based upon host cell type has been withdrawn. Accordingly, for example, Groups I-V have been consolidated in the elected Group I (and so forth for the other linked groups). This should address applicants concerns about the linking claim practice. Also, upon further consideration of the instant claims and specification, and in view of applicants' arguments, the requirement to elect a single peptide motif has been withdrawn. All of the peptide repeat sequence recited in the different groups have been rejoined.

With regard to remaining grounds for restriction between the larger groups (i.e. Groups I-V vs. Groups XV-XIV), these grounds remain in effect. This portion of the restriction requirement is still deemed proper and is therefore made FINAL.

Claims 1-20 are under consideration in the instant application, with claims 21-118 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a

nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the papers submitted 5/12/03 and 8/28/03.

### *Sequence Compliance*

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because sequences were set forth that lack sequence identifiers, no computer readable format (CRF) was filed, no paper sequence was filed and no attorney statement was filed. These sequences include **the oligonucleotide sequences in Figure 1B. If these sequences are present in the current sequence listing, it will only be necessary to amend the Brief Description of the Drawings to comprise the appropriate sequence identifiers.** If the Sequence Listing required for the instant application is identical to that of another application, a letter may be submitted requesting transfer of the previously filed sequence information to the instant application. For a sample letter requesting transfer of sequence information, refer to MPEP § 2422.05. Additionally, it is often convenient to identify sequences in figures by amending the Brief Description of the Drawings section (see MPEP § 2422.02).

Applicants are required to comply with all of the requirements of 37 CFR 1.821 through 1.825. Any response to this office action that fails to meet all of these requirements will be considered non-responsive. The nature of the noncompliance with the requirements of 37 C.F.R. 1.821 through 1.825 did not preclude the continued examination of the application on the merits, the results of which are communicated below.

***Information Disclosure Statements (IDS's)***

The information disclosure statements filed 1/14/03 and 1/17/02 fail to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Specifically, the non-patent literature references cited on each PTO Form 1449 are not present in the file. These references have not been considered and have not been initialed or crossed-off the PTO Form 1449's. The patent literature cited has been considered and the corresponding PTO 1449's have been mailed with this action.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in that the metes and bounds of the phrase "...providing a first pool of polynucleotides, said polynucleotides comprising at least two tandem repeats of sequences encoding said recombinant protein..." are unclear. First, does the phrase specify that the entire pool of polynucleotides comprises at least two tandem repeats, or does it specify that each of the polynucleotides comprises at least two tandem repeats? Second, does the phrase specify that each tandem repeat encodes the entire recombinant protein, or does it merely specify

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that the tandem repeats encode only a portion of the final, recombinant protein? It would be remedial to amend the claim language to explicitly address these two points.

Claim 3 is vague and indefinite in that the metes and bounds of the phrase “further comprising cleaving said recombinant protein between said tandem repeats to produce non-repeating peptides” are unclear. It is unclear whether the phrase is intended to specify cleavage of the polynucleotide, or of the recombinant protein produced by the method of claim 1.

Claims 12 and 15 specify a “targeting sequence” without any clarifying language as to what is targeted. Does the phrase mean the encoded protein is targeted to a particular portion of the host cell? Or does the phrase encompass a sequence that will direct the vector to a particular host cell type?

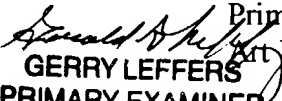
### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gerald G Leffers Jr., PhD  
Primary Examiner  
Art Unit 1636  
  
**GERRY LEFFERS**  
**PRIMARY EXAMINER**